

REMARKS

Applicants first wish to thank Examiner Woitach for the very helpful telephone interviews conducted on August 25, 2003 and September 5, 2003, and they present the amendment discussed in these interviews.

In the final Office Action mailed on February 24, 2003, claims 9, 11, and 20-23 were rejected under 35 U.S.C. § 112, first paragraph, claims 11, 23, 27, 28, 32, and 33 were rejected under 35 U.S.C. § 112, second paragraph, and claims 24, 25, 30, and 31 were objected to for being dependent on rejected claims. On June 9, 2003, Applicants filed a complete reply to the final Office Action. In the Advisory Action mailed on August 12, 2003, the Office stated that the claim amendments set forth in Applicants' June 9<sup>th</sup> reply would not be entered as the amendment to claim 9 raises new issues. Applicants now amend claim 9 to recite language which the Office, in the telephone interviews, has indicated would overcome the objection raised in the Advisory Action and would place the claims in condition for allowance. Applicants also add new claim 34, which recites claim language that the Office, in the telephone interviews, has indicated to be allowable. In addition, Applicants again address all issues raised in the final Office Action.

Claim Amendments

As required by the Office, Applicants have canceled claims 1-8, 10, and 12-19, which are directed to a non-elected invention. For the record, Applicants reserve the right to pursue these claims in a continuing application. In addition, in view of the amendments to claims 9 and 11, Applicants cancel claims 22, 23, and 30-33.

Claims 9, 11, 20, and 21 have been amended to recite the stringent hybridization conditions described, for example, at page 34, lines 2-6, of the specification. The remaining claim amendments simply clarify the claim language. Support for the term "substantially pure" in claim 11 may be found, for example, at page 15, lines 2-3.

New claim 34 finds support, for example, at page 25, lines 2-11, page 27, lines 9-17, page 34, lines 2-6, and page 35, line 20, to page 39, line 18, and new claims 35 and 36 find support, for example, at page 17, lines 14-18, and page 39, lines 10-18, of the specification.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 9, 11, and 20-23 were rejected under 35 U.S.C. § 112, first paragraph, for lack of written description in the specification. Claims 22 and 23 have been canceled and the rejection of these claims therefore is moot. Applicants address this rejection as applied to amended claims 9, 11, 20, and 21, as follows.

In response to Applicants' argument, presented in reply to the last Office Action,

that the present claims fall within the fact pattern of Example 9 of the U.S. Patent & Trademark Office's Written Description Guidelines ("the Guidelines") the Office stated (page 5):

[T]he specific facts in the present disclosure are not directly comparable to those set forth in the hypothetical examples because related species would not be identified with the single disclosed SEQ ID NO:2.

In support of this statement the Office pointed to Blakely et al. (Nature 354:66-70, 1991; "Blakely") and Sze et al. (Nature 403:560-564, 2000; "Sze") as providing serotonin-gated anion channel sequences with "sufficient amino acid sequence differences wherein the polynucleotide sequences encoding the serotonin-gated anion channel would not be identified with SEQ ID NO:2." In this regard, Applicants note that neither Blakely nor Sze teach a serotonin-gated anion channel nucleic acid sequence. Blakely provides the sequence for a serotonin transporter and Sze provides the sequence of a tryptophan hydroxylase which is involved in serotonin biosynthesis. As these sequences do not encode serotonin-gated anion channels, one skilled in the art would not expect them to hybridize to the complement of SEQ ID NO:2 under stringent conditions.

Moreover, the pending claims have been amended to recite the stringent hybridization conditions recited in canceled claims 22 and 23, and new claim 34 also recites these stringent conditions. The Office agreed that these hybridization conditions are stringent (see page 4), like those in Example 9. Thus, Applicants submit that the present claims, as amended, fall within the fact pattern set forth in Example 9 of the

**Guidelines.**

Furthermore, the Office asserted that the current case is analogous to *Ex parte Maizel*, 27 U.S.P.Q.2d 1662 (Board of Appeals and Interferences, 1992). Applicants disagree. The claim under consideration in *Ex parte Maizel* recited the phrase "or a biologically functional equivalent thereof," but provided no structural limitations for this functional equivalent. In contrast, the present claims require that the nucleic acid sequence that encodes a serotonin-gated anion channel hybridizes under stringent conditions to the complement of the sequence of SEQ ID NO:2 and that the serotonin-gated anion channel selectively permits passage of anions into or out of a cell, or across a membrane, in response to serotonin. Thus, unlike the claim in *Ex parte Maizel*, the present claims include both functional and structural limitations, and the current case therefore is not analogous to the cited case.

In view of the arguments set forth above, Applicants submit that the written description rejection of amended claims 9, 11, 20, and 21, and their dependent claims should be withdrawn and that new claims 34-36 also are free of this rejection.

**Rejection under 35 U.S.C. § 112, second paragraph**

Claims 11 and 23, and their dependent claims, were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite in their recitation of the phrase "purified serotonin-gated anion channel." In particular, the Office stated (page 9):

The ability of measuring a current flux is dependent on

generating a disequilibrium of ions on either side of the channel such as in the context of a cell, which can not be done with a purified protein.

Claim 23 has been canceled and the rejection of this claim therefore is moot. As amended, claim 11 now recites the phrase "substantially pure serotonin-gated anion channel." Applicants define a "substantially pure polypeptide" at page 15, lines 2-3, of the specification as being "a polypeptide that has been separated from the components that naturally accompany it." Thus, a substantially pure serotonin-gated anion channel may be expressed by a cell or be present in a membrane, and one skilled in the art would know how to measure current flux through such a channel. Applicants submit that the 35 U.S.C. § 112, second paragraph, rejection of claim 11 and its dependent claims should be withdrawn.

CONCLUSION

Applicants submit that the application is in condition for allowance and such action is hereby respectfully requested.

No fee is believed to be due. If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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